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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,668	09/07/2000	Jiangchun Xu	210121.484C3	2196

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EXAMINER
SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
1634	24

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/656,668	XU ET AL.	
	Examiner	Art Unit	
	Monika B Sheinberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,6-8,13,22,65 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,6-8,13,22,65 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

File copy

DETAILED ACTION

Response to RCE

Applicants' arguments, filed 17 September 2002, have been acknowledged and fully considered.

Claims 3, 4, 6-8, 13, 22, 65 and 66 are pending.

Declaration - 37 CFR § 1.132

The declaration under 37 CFR 1.132 faxed and filed 26 September 2002 (original copy was filed 27 September 2002) is insufficient to overcome the rejection of claims 3, 13, 22, 65 and 66 based upon 35 USC § 101 non-statutory subject matter due to lack of utility as set forth in the last Office action because: remains a deficient declaration of evidence of the comparison of ovarian tumorous and normal tissue due to the lack of evidence displaying any differences in expressional level or significant difference of expression levels between ovarian tumurous tissue and normal ovarian tissue. Further discussion is included below.

Priority

Applicant's claims for priority to US Patent applications 09/561,778 (05/01/2000) and 09/394,374 (09/10/1999) are acknowledged. However, these applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 3, 4, 6-8, 13, 22, and 65 of this application. The elected nucleic acid sequence, SEQ ID NO: 198 is not disclosed in either of these applications. Thus priority to these US Patent applications is not ~~considered~~. granted

Claim Rejections - 35 USC § 112/101

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 3, 4, 6-8, 13, 22, 65 and 66 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed nucleic acid, SEQ ID NO: 198, is not supported by a specific asserted utility because the disclosed use of this composition is not specific and is generally applicable to any nucleic acid. The specification states that the nucleic acid compound may be useful as a hybridization probe, primer, peptide encoding. However the claimed sequences falls short of a readily available utility. Similarly, protein may be used for antibody production, pharmaceutical compositions and vaccines. These are non-specific uses that are applicable to nucleic acid(s) and/or proteins in general and not particular or specific to the nucleic acid being claimed.

Unless the tumorous ovarian tissue is compared to normal ovarian tissue, no evidence exists that the sequence would not be detected in normal ovarian tissue as well, or at least at a significant difference than the tumorous ovarian tissue. The declaration of Paper No. 23 (filed 27 September 2002) only notions the comparison to normal ovarian tissue (p. 2, line 17) with no further evidence of significant expression level difference between the two. Applicants listed both in argument and in the declaration, evidence that "[l]ittle or no expression was observed in

normal [...]" detailed listing of various tissues other than ovarian (declaration, p. 2, lines 18-24). The specification and the declaration continue to lack disclosure whether or not the sequence is indicative of tumorous tissue that could be detected in any tissue or if it is specific only to ovarian tissue. This is not indicated by the comparison of tumorous ovarian tissue to various normal tissue (not including ovarian). If the sequence is expressed in normal ovarian tissue, the comparison between the expression levels of the tumorous ovarian tissue and normal ovarian tissue is not disclosed except the indication that one was done.

In addition, presuming full-length amplification, no piece or subset is disclosed for design of a suitable primer for the sequence amplification. No statement of the particular or suitable primer to be used for amplification is found within the specification. An oligonucleotide of 10 residues (claims 65 and 66) could bind under moderate stringency to nearly any region of a sequence that had at least 7-8 homologous residues besides a region that may possibly contain SEQ ID NO: 198; therefore amplifying an unknown and unpredictable product. Concerning the 50 contiguous nucleotides, no utility would result from detection unless the functional or active residues responsible for the ovary tumor-specificity are within that set of 50 bases. The specification does not teach or suggest which residues of the elected sequence, SEQ ID NO: 198, are responsible for the specific analysis or detection process claimed. Applicants argue that upon the over-expression of "all the residues of SEQ ID NO: 198" (p. 5, lines 23-24) then any 50 contiguous residues would be also over-expressed. This in itself is true, however, the claims include any sequence other than the SEQ ID NO: 198, containing at least 50 contiguous residues; thus an over-expression of the 50-contig could point to a sequence other than SEQ ID NO: 198.

The claimed nucleic acids, such as those of unlimited size consisting of at least 50 contiguous residues of SEQ ID NO: 198 are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain "the ovarian carcinoma protein" (specification, p. 2, lines 15-16). Besides there not being just one ovarian carcinoma protein, 210 contiguous nucleic acids of the SEQ ID NO: 198 are of 100% identity to GenBank accession number AI023799 (entered 28-AUG-1998), which is derived from a male liver and spleen organ. Applicants argue that the sequence has ovary tumor-specificity due to its identification from a POTS 2 library; however this library as described in the examples was created using only 3 patients of primary ovarian

tumors and 3 patients of metastatic ovarian tumors (p. 90, lines 10-19); thus not a representation of the population for establishing an absolute determinant of ovarian cancer diagnosis. Thus a lack of diagnostic utility as claimed. Table VII of the specification only discloses SEQ ID NO: 198 from chromosome 22 from the library POTS2. The selection of a sequence from a library and asserting an association to an ovarian carcinoma protein is not evidence of utility. The specification thus lacks a disclosure of any intrinsic utility or bioactivity of the elected sequence alone; such as if the sequence encodes a functional or useful domain of the peptide it encodes. The partial polypeptide encoded by the polynucleotide of claim 4, even though it may be an immunogenic portion, lacks utility in that a partial polypeptide sequence of a whole protein be it immunogenic or not, may not fold in the same fashion as that of the whole protein based upon presence or absence of other molecular interactions. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well established for the compounds.

Claims 3, 4, 6-8, 13, 22, 65 and 66 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility, or, alternatively, a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 4, 6-8, 13, 22, 65 and 66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 198, asserted to encode an ovarian carcinoma protein. The full-length exact sequence of SEQ ID NO: 198 per se meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 3, 13, 22, 65 and 66 are directed to encompass gene sequences that extend in both directions from SEQ ID NO: 198 in addition, they encompass sequences of any magnitude and/or content that comprise at least 50 contiguous residues of SEQ ID NO: 198; however the specification does not disclose each and every possible sequence that is encompassed by the claim. These sequences correspond to sequences from other species, mutated fragment sequences, allelic variants, splice variants, and so forth. None of these additional sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. This is a rejection based on a lack of WRITTEN DESCRIPTION.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 6-8, 13, 22, 65 and 66 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 13, 22, 65 and 66 are vague and indefinite due to the lack of clarity of the phrase "comprise a sequence selected from" as seen for example in claim 3, lines 1-2. It is unclear as to what are the metes and bounds of the parameters required for selection of a sequence of any magnitude and content that includes as little as 50 contiguous residues of SEQ

ID NO: 198 and can extend at variable length in both directions from the elected sequence. Claims 4 and 6-8 are also indefinite due to dependency from claim 3.

Claims 13, 65 and 66 are vague and indefinite due to the lack of clarity of the phrase "at least 90% identity to SEQ ID NO: 198" as seen for example in claim 13, line 5. It is unclear what are the metes and bounds of the parameters that define identity to the elected sequence: i.e. regions of a sequence of 10 base pairs, 9 of which are identical to SEQ ID NO: 198 would fulfill the requirement.

Claim 6 is vague and indefinite as to what is meant therein by the limitation "complementary". A possible interpretation is that the complement must be of the same length and be the full and exact complement of the recited SEQ ID NO: 198 sequence. Another interpretation is that any complement is meant including those with less than 100% complementarity, such as 90%, 50%, or even 10%. Clarification of the metes and bounds of the claim is requested via clearer claim wording. Claims 7 and 8 are rendered vague and indefinite due to dependency from the indefinite claim 6.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 65 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by the following two US Patents 5,585,232 (Farr; 17-Dec-1996) and 5,589,337 (Farr, 31-Dec-1996).

Farr teaches diagnostic kits in both US Patents using sequences (both SEQ ID NO: 2) that meet the limitations set in claims 65 and 66. US Patent 5,585,23 teaches in column 21, last paragraph the construction of the their primer sequence, SEQ ID NO: 2 through PCR techniques. The sequence is greater that 10 nucleotides in length, and with 100% identity, would hybridize under stringent conditions. US Patent 5,589,337 teaches the same in column 23, 3rd paragraph. Thus claim 65 is anticipated by Farr's two US Patents.

Conclusion

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 1 P.M to 8 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

November 29, 2002
Monika B. Sheinberg
Art Unit 1634

MBS

Jehanne Souaya
JEHANNE SOUAYA
PATENT EXAMINER